

TESTIMONY OF
BELINDA SIMONINI
MOTHER OF TITUS SIMONINI

HEARING ON
PRODUCT LIABILITY REFORM

IN THE

SUBCOMMITTEE ON
TELECOMMUNICATIONS, TRADE AND CONSUMER PROTECTION
COMMITTEE ON
COMMERCE
U.S. HOUSE OF REPRESENTATIVES

APRIL 8, 1997

PRODUCT LIABILITY HEARING
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Titus: "Testing 1,2,3,4,5,6,7,8,9,10 Testing, it works Mom"

Belinda: "Introduce yourself honey"

Titus: "Hi, my name is Titus. I live in San Diego and I have a shunt in my head, my Mom is going to tell you about it."

Belinda: "Hi, I'm Belinda Simonini, Titus' Mom, and I am very thankful to have him standing here with me today! Titus is a **very happy**, smart and active little boy but he had a very difficult start in life as he was born with Hydrocephalus, a congenital defect that affects approximately one in 500 children, and is more commonly known as "**water** on the brain". This "water" is actually Cerebral Spinal Fluid that our bodies normally produce, circulate throughout the spine and the brain and then reabsorb. When Hydrocephalus occurs there is too much of this fluid collecting in the ventricles of the brain, exerting pressure on the brain itself and causing harm to all of the brain's functions. Titus has a Delta Valve Shunt, like this one, manufactured by P.S. Medical. Shunt surgery is the most common operation in most neurological centers, and in pediatric centers, half of the procedures involve shunts. The shunt has a **small** valve which regulates the flow of fluid between the ventricle into which its inlet tubing is inserted and the outlet tubing which takes the excess fluid to another site in the body for reabsorption. In Titus' case his tubing **runs** to his abdominal cavity. The shunt works very well and has given Titus the ability to live the normal life that he has today.

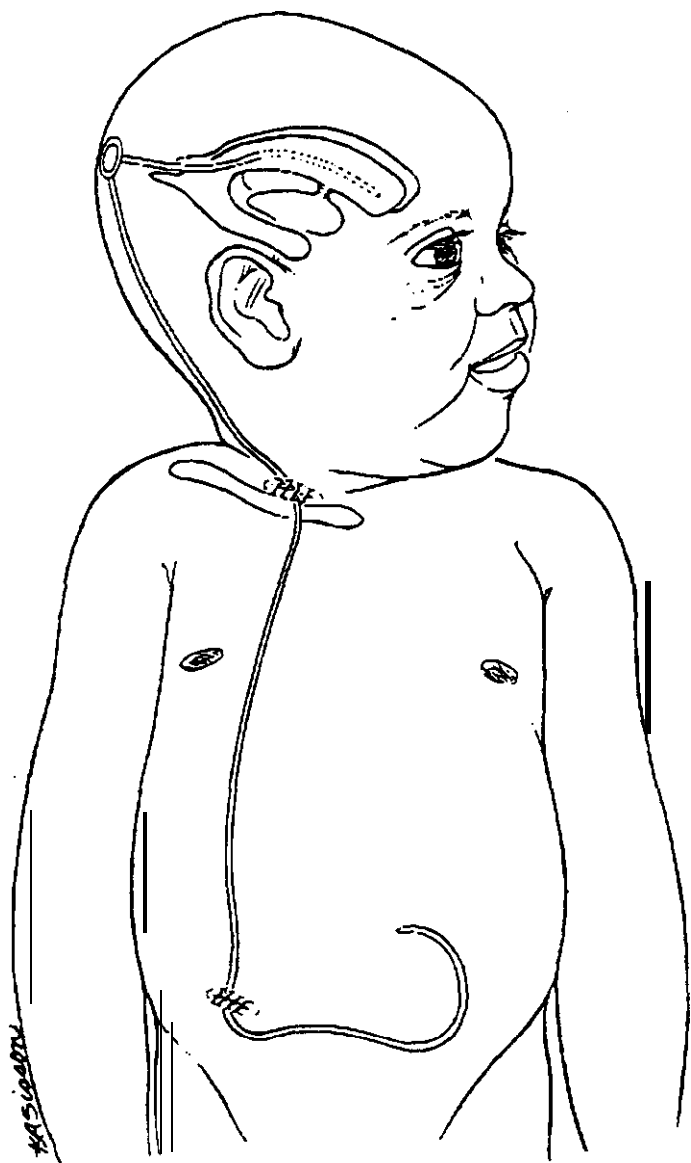
When Titus was born, the excess fluid in **his** brain had compressed his brain matter so severely that it appeared that he did not have all of his brain and that it was possibly not even structurally sound. With great urgency, his neurosurgeon, the late Dr. Prioleau of Kaiser, placed a shunt in his five pound body to drain the damaging fluid from his brain. Even with this treatment we were told that the extreme pressure had probably caused gross damage and to expect a child with **few** motor and mental capabilities, impaired vision and more. Six weeks after the surgery, when we took Titus back for an **MRI**, we found that his brain was all there and had rebounded completely. The shunt had worked phenomenally well! Now Titus **had** a chance to catch up and work towards developmental milestones with the aid of this device. Three years later the results are a true blessing, Titus is as bright, or more so, than the average three year old. It is a joy to take Titus anywhere where he will meet new people as he **truly** enjoys talking with them. We are always questioned as to how old he is because of his small frame coupled with his large vocabulary and inquisitive questions, and we sometimes refer to him as "**walkie** talkie". Titus will **enjoy** pursuing his gift for music and other normal activities in regular schools. Titus is really now healthy and strong and knows no limits. I credit God's good will and medical technology for his miraculous recovery.

The lifesaving shunts and the surgeons who are able to successfully implant them are what make lives like Titus' possible for the hundreds of thousands of people in our country who rely on a shunt. Before the **1950's** most children died of this heartbreaking condition. Without effective shunts their heads filled with fluid and grew to grotesque proportions sometimes even beyond the size of a basketball. These children quickly suffered from severe headaches, vision loss then blindness and eventually all of the disabilities from a **severly** damaged brain and finally death. In the early **1950's** silicone was first used in a new design created by John Holter, a father of a son with Hydrocephalus. The new silicone shunts worked much better and today the over 100 types of shunts available are all composed of and coated in hard silicone, very different from liquid silicone, products. This silicone is very expensive to produce and is made primarily by one company. Alternative sources will be very difficult to find and the shunts will become unavailable without the silicone.

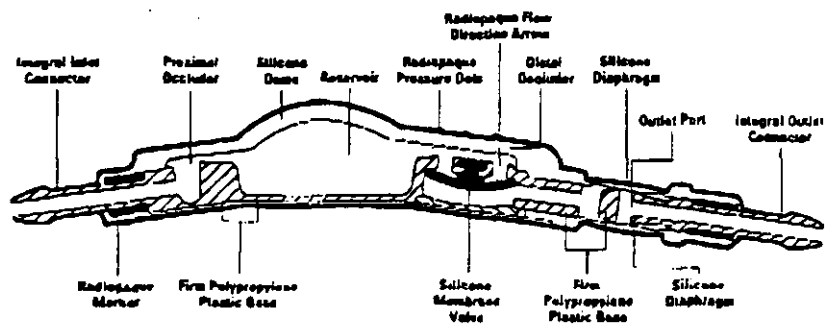
Shunts are the only viable treatment for the vast majority of Hydrocephalus patients, even so they hold the risk of occasional malfunction, **blockage** or infection. Titus will need another shunt at some time, as will the next baby born with hydrocephalus and the next premature baby that develops the need for **a** shunt as well as many accident and stroke victim's who will need a shunt to survive and recover. We as a society need to be sure that a shunt is available to all of these children and adults. As a mother, I am thrilled for Titus' miraculous health and prospects for the future but am terrified of the freighttrain of unbridled and misdirected litigation that threatens to eliminate the sources **of** silicone for the shunts to be made. Without a shunt our wonderful little boy would suffer a slow and painful deterioration leading to a heartbreaking death.

Titus is not alone, Jeffery Liakos, Mark Stephens, **Tara** Ransom and so many other children and adults live fruitful, active lives which should not be compromised, ever, by a shortage of shunts. There are over seven and a half million Americans as well that rely on implants to save and enhance their lives. These implants are as far ranging as simple sutures, tubing, and repair patches routinely used in surgery to Diagnostic Cardiac Catheterization to state of the art pacemakers, heart valves, intraocular lens for cataract patients, stimulators for bone growth, finger, knee and hip replacements and more which all **require some type of biomaterial** such as the special types of polyester, silicone, nylon, PTFE, **polyurathane** and polyethylene which are all at risk of becoming unavailable.

Reform **is** desperately needed to protect these biomaterial suppliers. Biomaterials legislation - which will not impair legitimate lawsuits and damages for faulty implantable devices - is before you. I urge you to support the Biomaterial Access Assurance Act and not allow lives like Titus' to be compromised! Titus might like to say something in closing." (Titus might, hopefully, sing **"Take me out to the ballgame" and say goodbye.**)



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